REMARKS

Applicants have filed this Amendment and Response in reply to an Official Action dated February 24, 2006 and Applicants believe that this Amendment and Response is fully responsive to the Official Action for at least the reasons set forth herein.

At the onset, Applicants would like to thank the Examiner for indicating that Claims 6-8 have allowable subject matter and would be allowed if rewritten in independent form including all of the limitations of the rejected base claim and all intervening claims. Accordingly, Claims 6-8 have been rewritten in independent format. Applicants submit that amended Claims 6-8 are allowable.

Additionally, Applicants note that Claims 1 and 3 have also been amended herewith. Claim 1 has been amended to specify that the claimed invention is directed to a puncture and penetration system. Accordingly, Claim 1 has been amended to recite that a puncturing probe has a pointed distal end portion that punctures a biological wall and penetrates through the biological wall. The claim also has been amended to recite that the outer cover also has a distal end portion that punctures the biological wall as the handpiece punctures the wall and penetrates through the biological wall as the handpiece penetrates the wall. Additionally, Claim 1 has been amended to include all of the limitations of original Claim 3.

Claim 3 has been amended to recite that the judgment of penetration is based upon a predetermined threshold value. Penetration is judging whether the impedance is below the predetermined threshold value.

No new matter has been added by way of the aforementioned amendments. For example, support therefor can be found in Figures 1 and 2, and pages 7, 9 and 14.

Applicants submit that amended Claim 1 is patentably distinct from all of the cited references in the outstanding Official Action, i.e, Sakurai et al. (hereinafter "Sakurai"), Costin, Sekino et al. (hereinafter "Sekino"), Ishikawa et al. (hereinafter "Ishikawa") and Edwards et al. (hereinafter Edwards).

Specifically, amended Claim 1 is directed to a ultrasound puncture system comprising, *inter alia*, a puncturing probe having a **pointed distal end portion** that **punctures** a biological wall and **penetrates** through said biological wall by transmitting ultrasound waves to the biological wall, which is to be punctured; an outer cover tube which covers the probe and is detachably attached to the handpiece, the outer cover tube having a **distal end portion** that **punctures** the biological wall as the handpiece punctures the biological wall, and **penetrates** through the biological wall as the handpiece penetrates trough the biological wall.

None of the cited references teach, suggest or render obvious, whether taken alone or in any combination thereof, an ultrasound system that includes a punctures probe and outer cover tube used for puncturing and penetrating a biological wall.

Sakurai teaches an ultrasound therapeutic apparatus for removing body tissue or fragment of a stone. The device does not have any pointed end portion as in the present invention. The probes' use is clearly different from the claimed use, i.e., to puncture the body tissue or further penetrate through the body tissue. One of ordinary skill in the art would not modify the system in Sakurai to include a pointed puncturing device since adding a puncturing device to Sakurai might damage the tissue, which Sakurai system is intended to heal.

Additionally, while both Sekino and Costin appear to disclose a pointed distal end portion of the probe, neither device (Sekino and Costin) discloses that this feature is used to puncture

and penetrate a biological wall. At best, the references describe that the pointed feature provides the probe better therapeutic functions.

Furthermore, while Costin states that the phaco needle 302 is adapted to come into contact with lens of the human eye, Costin does not state that the phaco needle is adapted to puncture or penetrate the lens of the human eye.

Additionally, neither Sekino nor Costin disclose an outer cover tube with a pointed distal portion.

Moreover, the cited references fail to teach a decision means for deciding that the probe has **penetrated** the biological wall based on the results of the operation means.

Sakurai teaches that the impedance is used to control or determine whether fluid is properly supplied to the probe. Sakurai does not teach that the impedance is used to decide or determine whether the probe has penetrated the biological wall. Additionally, since neither Costin nor Sekino mentions or accounts for puncturing and penetrating a biological wall with the probe, the references do not monitor whether the probe has penetrated through a wall.

Accordingly, Applicants submit that amended Claim 1 is patentably distinct from the cited references; as the references fail to teach, suggest or render obvious, each and every limitation of the claim.

Similarly, Applicants submit that Claim 3 is patentably distinct from the cited references based at least upon the above-identified reasons and further based upon the following analysis.

Applicants submit that the cited references fail to teach, suggest or render obvious that the penetration through said biological wall is judged based upon whether the impedance is below a predetermined threshold value.

None of the references teach using a threshold value to determine penetration. For example, Costin teaches using an impedance threshold value to determine the hardness or softness of an object that the needle comes into contact with. However, Costin does not teach using this threshold value for a determination of penetration.

Accordingly, Applicants submit that Claim 3 is patentably distinct from the cited references.

Claims 4 and 5 are patentably distinct from the cited references based at least upon their dependency from Claim 1 for at least the same reasoning as applied to Claim 1.

With respect to Claims 2 and 9, Applicants submit that the claims are patentably distinct from Sakurai, Costin and Sekino. Applicants respectfully disagree with the Examiner's § 103 rejection and traverse with at least the following analysis.

None of the references, whether taken alone or in any combination thereof, teach, suggest or render obvious the limitation of "the ultrasound power source unit comprises fluid supply means for supplying fluid", as recited in Claim 2 and "fluid supply means installed in the ultrasound power source unit...", as recited in Claim 9.

Sakurai teaches that the fluid supply means is a separate element from the power source unit. As depicted in Figure 1 elements 6 and 6a, the fluid supply means is separate from element 40. The fluid supply means 6 is directly attached to the handpiece. One end of the water supply tube is connected to the outer end of the water supply connector 27. The other end is connected to the water cooling tank. The water tank, water supply pump and water supply tube provide cooling water to the water supply passage for the sheath (Col. 5, lines 3-15). The water pump is driven to supply water from the water supply tube into the water supply passage. The water is

fed into the body cavity and is sucked through a first suction passage after it has washed the body cavity clean.

In contrast, Claims 2 and 9 are directed to a fluid supply means installed in the ultrasound power source unit.

In an embodiment of the invention, the specification describes that a pump 24 is contained in the power source unit 3, one end of the pump being connected to a fluid tank 5 and the other end being connected to a fluid supply connector 16. The fluid present in the fluid tank 5 is supplied by the pump 24 to the socket 14 of the outer cover tube 10 via the tube 15 connected to the fluid supply connector 16. From the socket 14, the fluid can be further supplied into the opening 23 at the distal end side via the clearance 22 of the outer cover tube 10 formed by the ultrasound probe 9 inserted therein (Pages 9-10). The fluid is used to prevent any foreign matter such as body fluids or tissue from penetrating to the periphery of the distal end portion.

Sekino and Costin fail to cure these deficiencies.

Accordingly, Applicants submit that none of the references teach that the fluid supply means is located within the power source unit. Therefore, Claims 2 and 9 are patentably distinct from the cited references, as the reference fail to teach, suggest or render obvious, each and every limitation of the claims.

Applicants also respectfully disagree with the Examiner's § 103 rejection of Claim 10 and traverse with at least the following analysis. Applicants submit that the Sakurai, Sekino and Costin fail to teach an electrode disposed on the biological wall which is to be punctured with the distal end portion of the probe as recited in Claim 10. In fact, the Examiner neither addressed this limitation in the Official Action nor pointed to any support in any reference. Applicants

invite the Examiner to identify the references that teach the feature in issue (and the specific location within the reference).

The instant specification describes that one of the terminals of the insulating transformer forming the insulating means 73 is connected to **an electrode 75 applied (e.g., pasted) to the skin tissue 21 in the vicinity of the zone where the treatment by puncturing with the distal end of probe 9** is conducted. The inductance of the skin is measured between the probes and the electrode. In this case, the skin tissue 21 which is in contact with the distal end portion 9a is present between the probe 9 and electrode 75 because the puncture treatment is conducted by the distal end portion 9a of the probe 9, and an extremely high impedance is obtained when the skin tissue 24 is pierced by the distal end portion 9a of the probe 9 and the contact (with the skin tissue 24 at the instant the puncture has been conducted) is lost. See page 30.

Accordingly, Applicants submit that the Sakurai, Sekino and Costin fail to teach an electrode disposed on the biological wall, which is to be punctured with the distal end portion of the probe. Therefore, Claim 10 is patentably distinct from the cited references, as the reference fails to teach, suggest or render obvious, each and every limitation of the claims.

For all the foregoing reasons, the Applicants respectfully request the Examiner to withdraw the rejections of Claims 1-5, 9 and 10 pursuant to 35 U.S.C. § 103(a).

In conclusion, the Applicants believe that the above-identified application is in condition for allowance and henceforth respectfully solicit the Examiner to allow the application. If the Examiner believes a telephone conference might expedite the allowance of this application, the

Applicants respectfully request that the Examiner call the undersigned, Applicants' attorney, at the following telephone number: (516) 742-4343.

Respectfully submitted,

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